## **REMARKS**

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## I. General

Claims 26 and 29 - 39 are presently pending in the application. The issues in the current Office Action are as follows:

- Claims 26, 29, 35, 36 and 48 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,167,752 to Lin-Hendel (hereinafter, "Lin-Hendel").
- Claims 30 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above.
- Claim 33 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above, and further in view of U.S. Patent No. 5,891,182 to Fleming (hereinafter, "Fleming").
- Claims 37 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 36 above, and further in view of U.S. Patent Publication No. 2002/0099412 to Fischell et al. (hereinafter, "Fischell").
- Claim 39 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 35 above, and further in view of U.S. Patent No. 4,982,742 to Claude et al. (hereinafter, "Claude").

Applicant appreciates the courtesy and professionalism extended by the Examiner thus far. Applicant hereby traverses the rejections and requests reconsideration and withdrawal in light of the amendments and remarks contained herein.

### II. Claim Status

The Examiner has objected to the amendment of the claims filed November 12, 2010 as not complying with the requirements of 37 CFR 1.121(c) because claim 34 was identified

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as "Previously Presented," whereas in the previous amendment, the claim was identified as "Withdrawn." Applicant has correctly indicated that claim 34 is withdrawn in this response.

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## III. Claim Amendments

Claim 29 has been amended to recite "A device for treating damaged tissue . . . ." Support for this amendment to claim 29 may be found at least at paragraph [0001] of the published application. Claim 29 has also been amended to positively recite that the dressing has a treatment surface. Further, claim 29 has been amended to recite "constantly and concurrently varying the value of the amplitude of the alternating current and the frequency of the alternating current to electrically stimulate and repair said damaged tissue." Support for this amendment to claim 29 may be found at least at paragraph [0117], Fig. 6 and Table 1 of the published application. Claim 48 has been canceled. No new matter has been added by these amendments.

#### IV. Claim Rejections

### A. 35 U.S.C. § 102(e) Rejection (Lin-Hendel)

Claims 26, 29, 35, 36 and 48 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lin-Hendel. In order for a claim to be anticipated under 35 U.S.C. § 102, "[t]he *identical invention* must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) (emphasis added). Moreover, "[t]he elements must be arranged as required by the claim . . ." M.P.E.P. § 2131 citing *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). The Applicant discusses the rejected claims below.

# 1. Independent claim 29

Claim 29, as amended, requires "a control unit for passing alternating current to the treatment area via the electrodes and for constantly and concurrently varying the value of the amplitude of the alternating current and the frequency of the alternating current to electrically stimulate and repair said damaged tissue." The Examiner (in the rejection of claim 48) refers to col. 4, lines 54 - 64 of Lin-Hendel as a disclosure of constant variation of amplitude and

frequency. Office Action, page 3. However, the Examiner's reliance on this disclosure of Lin-Hendel is misplaced. Whilst amplitude and frequency are mentioned at col. 4, lines 54 – 64, there is no disclosure there of constant variation of both amplitude and frequency.

This is confirmed by the signal representations shown in the figures of Lin-Hendel. Specifically Figure 8A (fourth from bottom, and bottom figures only) show only a constant variation (*i.e.* continual variation) of amplitude, but do not show any constant variation (*i.e.* continual variation) of frequency. The same is true of Figure 8B (second and third figures) which show, at the most, a constant variation of amplitude, but not of frequency. None of the signal representations shown in any of the figures in Lin-Hendel show any form of constant variation of frequency.

Furthermore, claim 29 requires that the constant variation of amplitude and frequency be done concurrently. The synergistic combination of the constant variation of both amplitude and frequency is an aspect of the invention not disclosed or even suggested by Lin-Hendel. In fact, the European Patent Office has recently found that this aspect of the invention to be sufficient distinction of the invention *vis-à-vis* prior art. Accordingly, the European Patent Office has issued a notice of allowance for a claim similar to that proposed by amended claim 29. It should be noted that paragraph [0070] of the published application states that "It has been found that constantly varying the amplitude and/or the frequency of the alternating current provides enhanced tissue regeneration over previously known methods of electrical tissue stimulation." Lin-Hendel's disclosure does not recognize or contemplate this benefit of this aspect of the invention. Thus, one skilled in the art would have no reason to modify Lin-Hendel to meet the limitations of claim 29.

At least because Lin-Hendel fails to teach or suggest a control unit for constantly and concurrently varying the value of the amplitude and the frequency of the alternating current to electrically stimulate and repair damaged tissue, claim 29 is patentable over Lin-Hendel.

Claim 29 also requires "a dressing." Paragraphs [0103] and [0104] and Figs. 2A and 2B provide examples of a dressing. Further, a dressing is well known to be protective material that is applied to a wound or to tissue that has been damaged through trauma (*e.g.* a gauze-type dressing applied to open wounds or burns, or a bandage applied to tissue 65585328.1

surrounding an injured muscle, ligament or tendon). The Examiner relies on Lin-Hendel, col. 5, lines 4-8 for teaching a dressing. Col. 5, lines 4-8, however, describe conductive gelpads. The conductive gel pads of Lin-Hendel provide no protection to a wound or to tissue that has been damaged through trauma. The conductive pads are merely present to pass a magnetic field into the body from electrodes contained within them. As such, the conductive gel pads of Lin-Hendel cannot be properly construed as a dressing having a treatment surface.

Moreover, modifying Lin-Hendel's device to have a dressing would conflict with Lin-Hendel's objective of injecting energy into Acu-Points where needles would normally be inserted in acupuncture. See Lin-Hendel, col. 4, lines 24 – 31. Specifically, the use of a dressing would cover a larger area than an Acu-Point and thereby prevent the correct identification of a desired Acu-Point position for injection. See e.g. Figs. 1A – 1D (showing precise positions of Acu-Points on the body). Thus, apart from not anticipating claim 29, Lin-Hendel is not a reference that is suitable for modification to meet claim 29. See M.P.E.P. § 2143.01 citing In re Ratti, 123 U.S.P.Q. 349 (CCPA 1959) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.").

Furthermore, claim 29 requires "a dressing having a treatment surface for applying to a treatment area of said damaged tissue; a pair of electrodes affixed on said treatment surface of the dressing . . . ." (Emphasis added). Lin-Hendel does not describe a treatment surface for applying to a treatment area of damaged tissue, wherein electrodes are affixed on the treatment surface. The conductive gel pads (the asserted dressing) are described as having coil-shaped electrodes embedded within them. See Lin-Hendel col. 5, lines 4 to 7. These electrodes pass a magnetic field through the pads and cannot be applied directly to the treatment area for passing an electric current to electrically stimulate and repair damaged tissue (as required by claim 29). Id. Rather, the electrodes in Lin-Hendel pass a magnetic field through the pads. Id. The difference between electrical stimulation and magnetic stimulation is significant. As such, the Examiner has not shown Lin-Hendel teaches the limitations of claim 29 at issue. In sum, Lin-Hendel fails to teach "a dressing having a

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treatment surface for applying to a treatment area of said damaged tissue; a pair of electrodes affixed on said treatment surface of the dressing . . . ."

Because, as discussed above, Lin-Hendel does not disclose a plurality of the limitations of claim 29, Lin-Hendel is clearly not identical to claim 29. Indeed, considering the devices as a whole, the device of claim 29 is fundamentally different from the device disclosed in Lin-Hendel. Thus, Lin-Hendel's device would not even be a device that one skilled in the art would seek to modify to meet claim 29. For instance, Lin-Hendel's device is not concerned with repair of damaged tissue. Instead, Lin-Hendel relates only to a replacement for acupuncture treatment which, according to Lin-Hendel at col. 2, lines 49 – 55 is: "a widely practiced traditional Chinese healing/therapeutic modality, literally called Finger Pressure in Chinese. This modality uses fingers to apply pressure to, and/or massage the Acu-Points to heal ailments or to enhance health, largely using the same 'indications' as in Acupuncture." This is completely different to repair of damaged tissue, such as wounds and trauma. As such, one skilled in the art would recognize that Lin-Hendel is a completely different device from claim 29 and would not be inclined to consider Lin-Hendel as a basis for modification to meet claim 29.

In sum, Lin-Hendel does not anticipate claim 29 or provide a basis for modification to meet claim 29. Accordingly, Applicant respectfully requests the withdrawal of the 35 U.S.C. § 102(e) rejection of claim 29 and allow this claim.

#### 2. Dependent claims 26, 35, 36 and 48

Claim 48 has been canceled. Dependent claims 26, 35 and 36 depend either directly or indirectly from independent claim 29, and thus inherit all of the limitations of claim 29. It is respectfully submitted that dependent claims 26, 35 and 36 are patentable at least because of their dependence from independent claim 29 for the reasons discussed above.

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<sup>&</sup>lt;sup>1</sup> Damaged tissue is described in the published application, paragraph [0002] as being tissue which is subject to damage including: "non-complicated acute wounding, complicated chronic wounding, trauma, exercise related trauma and pathological damage." Furthermore, repair of damaged tissue involves regeneration of tissue cells. *See* Published application, paragraph [0004].

Moreover, the dependent claims recite limitations that the Examiner has not shown to be taught by the cited art. Claim 26, for example, requires that "the control unit and the dressing are integrated with each other." The Examiner relies of Lin-Hendel, Fig. 7 for teaching this limitation of claim 26. Fig. 7, however, does not even show the conductive gel pads (the asserted dressing), let alone show that it is integrated with items 76, 77, 78, 79 and 701 (the asserted control circuitry). As such, the Examiner has not shown that Lin-Hendel describes all the limitations of claim 26.

In sum, the Examiner the Examiner has not shown that Lin-Hendel describes that identical invention as claims 26, 35 and 36. Accordingly, Applicant respectfully requests the withdrawal of the 35 U.S.C. § 102(e) rejection of claims 26, 35 and 36.

## B. 35 U.S.C. § 103(a) Rejection over Lin-Hendel

Claims 30 – 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above. In an obviousness rejection, "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 15 – 17 (1966). The Applicant discusses below why the rejected claims are patentable over Lin-Hendel.

Dependent claims 30 - 32 depend from independent claim 29 and thus inherit all the limitations of claim 29. As discussed above, Lin-Hendel does not teach all the limitations of claim 29. Therefore, it is respectfully submitted that dependent claims 30 - 32 are allowable at least because of their dependence from claim 29 for the reasons discussed above.

Moreover, the dependent claims recite limitations that the Examiner has not shown to be taught or suggested by the cited art. Claim 30, for example, requires "the alternating current is varied between 50 and 500 microamps." Further, based on the limitations inherited from claim 29, the variation between 50 and 500 microamps must be done constantly. The Examiner relies on Lin-Hendel, col. 6, lines 57 – 58 for teaching this limitation of claim 30. Office Action, page 4. The cited portion of Lin-Hendel, however, merely teaches that the current used in the Lin-Hendel device may range from a few mAmps to 200 mAmps. This is

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insufficient to teach constantly varying the alternating current between 50 and 500 microamps. In other words, the mere fact that the Lin-Hendel device may be operated with any current between a few mAmps and 200 mAmps does not teach constantly varying the alternating current between 50 and 500 microamps.

Claim 31 requires, "the frequency of the alternating current is varied between 10 and 900 hertz." Further, based on the limitations inherited from claim 29, the variation between 10 and 900 hertz must be done constantly. The Examiner relies on Lin-Hendel, col. 6, lines 50 - 52 for teaching this limitation of claim 31. Office Action, page 4. The cited portion of Lin-Hendel, however, merely teaches that the electrical impulses used in the Lin-Hendel device may range from 0.5 Hz to 200 Hz. This is insufficient to teach constantly varying the alternating current between 10 and 900 hertz. In other words, the mere fact that the Lin-Hendel device may be operated using electrical current between 0.5 Hz to 200 Hz does not teach constantly varying the alternating current between 10 and 900 hertz.

Claim 32 requires, "the time period between each variation of amplitude is 0.1 s."

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to modify the time period between each variation of amplitude because discovering an optimum value involves only routine skill in the art. Office Action, page 4. The Examiner, however, has not established why one skilled in the art would attempt to vary the time period in order to arrive at the claim limitation where the time period between each variation of amplitude is 0.1s. Instead, the Examiner has merely used the current disclosure about varying amplitude to assert that one skilled in the art could optimize and arrive at the time period recited in the claim. Using the current application as the roadmap for rejecting its claims is inappropriate. Sensonics Inc. v. Aerosonic Corp., 81 F.3d 1566, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction — an illogical and inappropriate process by which to determine patentability.").

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In sum, the Examiner has failed to show that claims 30 - 32 are obvious. Accordingly, Applicant respectfully requests the withdrawal of the 35 U.S.C. § 103(a) rejection of claims 30 - 32.

## C. 35 U.S.C. § 103(a) Rejection over Lin-Hendel in view of Fleming

Claim 33 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 29 above, and further in view of Fleming. As discussed above, Lin-Hendel does not teach all the limitations of claim 29. Fleming is not relied on and does not appear to cure this deficiency of Lin-Hendel. It is respectfully submitted that dependent claim 33 is allowable at least because of its dependence from claim 29 for the reasons discussed above.

## D. 35 U.S.C. § 103(a) Rejection over Lin-Hendel further in view of Fischell

Claims 37 and 38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 36 above, and further in view of Fischell. Dependent claims 37 and 38 depend indirectly from independent claim 29 and thus inherit all the limitations of claim 29. As discussed above, Lin-Hendel does not teach all the limitations of claim 29. Fischell is not relied on and does not appear to cure this deficiency of Lin-Hendel. Therefore, it is respectfully submitted that dependent claims 37 and 38 are allowable at least because of their dependence from claim 29 for the reasons discussed above. Accordingly, Applicant respectfully requests the withdrawal of the 35 U.S.C. § 103(a) rejection of claims 37 and 38.

### E. 35 U.S.C. § 103(a) Rejection over Lin-Hendel further in view of Claude

Claim 39 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Lin-Hendel, as applied to claim 35 above, and further in view of Claude. As discussed above, Lin-Hendel does not teach all the limitations of claim 29. Claude is not relied on and does not appear to cure this deficiency of Lin-Hendel. Therefore, it is respectfully submitted that dependent claim 39 is allowable at least because of its dependence from claim 29 for the reasons discussed above. Accordingly, Applicant respectfully requests the withdrawal of the 35 U.S.C. § 103(a) rejection of claim 39.

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# V. Conclusion

In view of the above, Applicant believes the pending application is in condition for allowance and respectfully requests favorable reconsideration. The fee of \$245.00 set forth under 37 CFR 1.17(a)(2) for a two-month extension for response and the fee of \$405.00 set forth under 37 CFR 1.17(e) for filing the accompanying Request for Continuing Examination for a small entity will be paid by credit card. Please charge any additional fees required or credit any overpayment to Deposit Account No. 06-2380, under Order No. 51407/P029US/10605267 during the pendency of this Application pursuant to 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees.

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Respectfully submitted,

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